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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,498	09/20/2006	Tanja Bendele	903-196 PCT/US/RCE	8290
23869 7590 10/19/2009 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER RUMP, RICHARD M	
			ART UNIT	PAPER NUMBER
			1793	
			MAIL DATE	DELIVERY MODE
			10/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,498	Applicant(s) BENDELE ET AL.	
	Examiner Richard M. Rump	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

Claims 1-8 and 10-21 are pending and presented for examination. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 September 2009 has been entered.

Claim Rejections - 35 USC §§ 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 4-8 & 10-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Brittan, "Effects of Mechanical Processing on Phase Composition".

Regarding claims 1-2, 4-6, 8, 10, 13-21, Brittain discloses the milling of pharmaceuticals (chlorpropamide) and how that results in the formation of differing polymorphs (1577 left hand 2nd paragraph; Section 'Effects due to Particle Size Reduction') via high energy transmission. There is a co-crystal transformation of a crystalline phase done between two polymorphs at the solid interfaces (1577 left hand 3rd paragraph). Also see section entitled, "Mechanical Activation of Solids". While there

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is no direct mentioning of this being a high energy milling, a skilled artisan when looking at the entire disclosure would arrive find it obvious that the high energy transmission is achievable through milling, especially given the subjectivity of the term 'high'.

Regarding claim 7, an amorphous phase may be utilized (*Id.*).

Regarding claim 11, the process can obviously be done in a batch, continuously, or semi-continuously given the nature of milling.

Regarding claims 12-14, relative humidity is mentioned which implies an atmosphere, pressure and temperature (*Id.*; 1574 left hand column 2nd paragraph).

Regarding claim 15, while Brittain does not expressly state that the next polymorph will have a greater density, a skilled artisan would find it obvious to perform the milling to create any polymorph, especially given that the disclosed pharmaceutical has 32 possible polymorphs.

Allowable Subject Matter

Claims 3 & 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No cited prior art either alone or in combination discloses or reasonably suggests using forces between 35 g and greater; nor milling speeds greater than 14 m/s.

Response to Arguments

Applicant's arguments with respect to claims 1-8 and 10-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 1-8 & 10-21 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard M. Rump whose telephone number is (571) 270-5848. The examiner can normally be reached on Monday through Friday 7:00 AM-4:30 PM (-5 GMT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on (571)272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. M. R./
Examiner, Art Unit 1793

/Stuart Hendrickson/
Primary Examiner, Art Unit 1793